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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
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EXAMINER
GAMBEL, P

ART UNIT	PAPER NUMBER
1644	15

DATE MAILED: 08/17/98

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☐ Responsive to communication(s) filed on 1/8/98, 4/16/98
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☐ Claim(s) 29-37 is/are pending in the application.
- Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 29-37 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claims _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of Reference Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 12
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

DETAILED ACTION

1. The location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1644, Group 1640, Technology Center 1600.

2. Applicant's amendment, filed 4/16/98 (Paper No. 14), is acknowledged.

Claims 1-28 have been canceled previously.

Claims 29-37 are pending and being acted upon presently.

3. The text of those sections of Title 35 USC not included in this Action can be found in prior Actions.

4. Formal drawings and photographs have been submitted which fail to comply with 37 CFR 1.84. Please see the form PTO-948 previously sent in Paper No. 7.

Formal figures will be submitted upon indication that this application is allowable.

5. In view of the papers filed 1/8/97 (Paper No. 13); it has been found that this application, as filed, without any deceptive intent, improperly set forth the inventorship, and accordingly, this application has been corrected in compliance with 37 C.F.R. § 1.48. The inventorship of this application has been changed by adding Cheryl Heard as an inventor. The instant inventors are Anderson, Hanna, Brams and Heard.

6. Upon reconsideration of applicant's arguments, filed 4/16/98 (Paper No. 14); the previous rejection under 35 U.S.C. § 102(b) as being anticipated by Razi-Wolf et al. (PNAS, 1992) as it applies to the instant claims has been withdrawn.

7. Upon reconsideration of applicant's arguments, filed 4/16/98 (Paper No. 14); the previous rejection under 35 U.S.C. § 102(b) as being anticipated by Valle et al. (Immunology, 1990) as it applies to the instant claims has been withdrawn.

8. Upon reconsideration of an updated search and in view of compact prosecution; the previous rejection under 35 U.S.C. § 102(b) as being anticipated by Van Gool et al. (Blood, 1994) has been replaced by de Boer et al. (U.S. Patent No. 5,747,034), which provides a more complete characterization of the B7-specific antibody B7-24, referenced in Van Gool et al.

9. Upon reconsideration of applicant's arguments, filed 4/16/98 (Paper No. 14) with respect to Razi-Wolf et al. (PNAS, 1992) OR Valle et al. (Immunology, 1990) and upon reconsideration of an updated search with respect to Van Gool et al. (Blood, 1994); the previous rejection under 35 U.S.C. § 103 has been withdrawn.

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371^o of this title before the invention thereof by the applicant for patent.

11. Claims 29-32, 34 and 37 are rejected under 35 U.S.C. § 102(e) as being anticipated by de Boer et al. (U.S. Patent No. 5,747,034). De Boer et al. teach human B71-specific antibodies, including B7-24, that bind an epitope that differs from the prior art B7-specific antibodies, wherein the specificity inhibits CD28 binding and T cell activation but differs from a CTLA-4 binding epitope (see entire document; including column 5, lines 49-65; column 6, lines 24-41; column 25, lines 28-30; columns 27-28, Example 14). In addition, this reference teaches various recombinant forms of said antibodies and pharmaceutical compositions thereof (columns 7-16). Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention

12. Claims 29-37 are rejected over by de Boer et al. (U.S. Patent No. 5,747,034) in view of art-known procedures and motivation to generate recombinant antibodies (e.g. humanized, chimeric or primatized) for diagnostic and therapeutic regimens as acknowledged on pages 15-20 and 24-27 of the specification (e.g. Newman et al. Biotechnology, 1992)

De Boer et al. teaches B71-specific antibodies, recombinant forms and pharmaceutical compositions of said antibodies as set forth above in section 11. De Boer et al. differ from the instant claims by not disclosing the art known use of primatized (as it differs from humanized) forms of recombinant antibodies.

In agreement with the specification, it was well known in the art at the time the invention was made to chimerize/primatize/humanize antibodies to have readily available reagents suitable for human diagnosis and therapy and their respective use in primate models. For example, Newman et al. teach the protocols of primatizing antibodies including the use of computer analysis of the instant invention (see entire document). The recombinant techniques and computer analyses of immunoglobulin sequences as taught by the references would have resulted in the same or very nearly the same characteristics of the instant claims since both the references and instant invention use the same techniques, the same antibody specificities and the same goals. The ordinary artisan would have achieved either the same or functional equivalents of the instant B7.1-specific antibodies, as such properties are taught by De Boer et al.. Also, note that the claims do not require that one generates the exact same antibody as the instantly disclosed 7C10 and 16C10 antibodies, but rather isolates an antibody that has the same functional characteristics as said antibodies. The claimed functional limitations are properties of the referenced B7-specific inhibitory antibodies.

One of ordinary skill in the art at the time the invention was made would have been motivated to select recombinant B7.1-specific antibodies, including primatized antibodies, as diagnostic and therapeutic agents in treating human immunoregulatory disorders. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

13. Claim 34 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 34 is indefinite in the recitation of "chimeric mal/human" because its characteristics are unclear and the recitation of "mal" is unknown. Further, it is noted that chimeric antibodies is an ambiguous phrase that encompasses any number of recombinant forms of antibodies and the claim does not clearly set forth the metes and bounds of the "chimeric antibodies" encompassed by the claimed invention. For example, generally chimeric would refer simply to variable (e.g. murine) region - constant region (e.g. human) constructs, while humanized antibodies which are also chimeric would refer to CDR-grafted antibodies. Applicant is invited to amend the claims to clearly set forth the structural features of the claimed chimeric antibodies, encompassed by the claimed invention.

The applicant is reminded that the amendment must point to a basis in the specification so as not to add any new matter

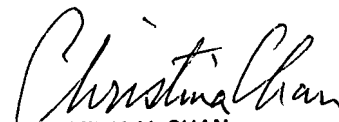
14. No claim is allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.



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August 17, 1998



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